

State of Alaska
Department of Commerce, Community and Economic Development
Division of Corporations, Business and Professional Licensing

Alaska Board of Pharmacy

DRAFT MINUTES OF THE MEETING
February 28 – March 2, 2018

By authority of AS 08.01.070(2), and in compliance with the provisions of AS 44.62, Article 6, a scheduled meeting of the Board of Pharmacy was held via WebEx and at the State Office Building, Conference Room A in Juneau, Alaska on February 28 – March 2, 2018.

These are draft minutes that have not yet been approved by the board.

Agenda Item 1 Call to Order/Roll Call Time: 9:43 a.m.

The **February 28, 2018**, meeting day was called to order by Chair, Leif Holm at 9:43 a.m.

Board members present, constituting a quorum:

Leif Holm, PharmD #PHAP1606 – *Chair*
Richard Holt, PharmD #PHAP2008, MBA – *Vice Chair*
Phil Sanders, RPh #PHAP776
James Henderson, RPh #PHAP1683
Anne Gruening, Public Member
Lana Bell, RPh #PHAP893
Tammy Lindemuth, Public Member
Sharon Long, Public Member (effective 03/01/2018; via phone)

Division staff present:

Donna Bellino, Occupational Licensing Examiner
Laura Carrillo, Records & Licensing Supervisor
Melissa Dumas, Administrative Officer
Marilyn Zimmerman, Paralegal
Brian Howes, Investigator

Public members present:

Greg Estep, #PHAP2259, Walgreens (via phone)

Lis Houchen, NW Regional Director, National Association of Chain Drug Stores
Caren Robinson, Alaska Pharmacists Association

Agenda Item 2 Review/Approve Agenda

Time: 9:44 a.m.

Chair Holm prompted the board to review the agenda. There were no suggested additions or Amendments for February 28, 2018.

On a motion duly made by Lana Bell, seconded by Anne Gruening, and approved unanimously, it was

RESOLVED to accept the February 28, 2018, agenda as written.

Agenda Item 3 Review/Approve Minutes

Time: 9:44 a.m.

The board addressed the meeting minutes from the November 30 – December 1, 2017, meeting and took time to review the draft minutes.

On a motion duly made by Lana Bell, seconded by James Henderson and approved unanimously, it was:

RESOLVED to approve the November 30 – December 1, 2017, meeting minutes as written.

Agenda Item 4 Ethics Disclosures

Time: 9:48 a.m.

Hearing nothing further on meeting minutes, Chair Holm prompted the board to disclose ethics issues. There were no ethics matters to disclose.

Agenda Item 5 Investigative Report

Time: 9:30 a.m.

Brian Howes joined the room telephonically at 9:44 a.m.

Investigator, Brian Howes provided his investigative report for the February 28 – March 2, 2018, which included the period of November 15, 2017, through February 7, 2018. Brian Howes informed the board that the division opened four (4) files and closed seven (7) matters, with eight (8) cases still open as reflected on the investigative memorandum provided to the board.

Rich Holt inquired to Mr. Howes as to whether they would have an update on some of the matters that were opened in 2016, to which Mr. Howes responded that these matters will likely be discussed at the board's next meeting.

Chair Holm commented on the 2016 open cases, inquiring whether there were specific hang-ups delaying resolution of these outstanding matters. Mr. Howes indicated that some of the matters would be resolved and that some may carry additional charges. Chair Holm commented that the drug diversion matter should be having more momentum and Rich Holt added that the unresolved two-year unprofessional conduct case should be resolved. Speaking on this delay, Chair Holm reiterated legislative audit's previous findings that investigative matters were not being resolved in a timely manner. Chair Holm acknowledged the work load Mr. Howes has with investigations relating to pharmacy as well as to the Prescription Drug Monitoring Program (PDMP), but encouraged close follow-up with these cases to be resolved more timely.

Brian Howes left the room telephonically at 9:55 a.m.

Agenda Item 6 Public Comment

Time: 9:53 a.m.

Hearing nothing further on investigations, Chair Holm entertained review of public comments. As indicated at the board's previous meeting, no oral public comments on the proposed SB 74 regulations, PDMP fees, and various changes to licensure requirements, collaborative practice, refills, wholesale distributor licensing, and disciplinary actions were going to be heard at this time. Before reviewing written public comments submitted to the regulations specialist and in the interest of time, Chair Holm called for Caren Robinson to present on behalf of the Alaska Pharmacist Association.

Agenda Item 12 Pharmacy Industry Update

Time: 9:55 a.m.

Alaska Pharmacists Association

Addressing the pharmacy industry update, Caren Robinson with the Alaska Pharmacists Association presented to the board a summary of the bills supported by the association as well as an update on pharmacy school student activities. Ms. Robinson informed the board that ten (10) pharmacy school students will be attending the senior center to do vaccinations and will be here on Friday to shadow the board's meeting on Friday, March 2nd. Ms. Robinson reviewed Senate Bill 32 (the bill addressing biologics), HB 240 (fair audit bill), and Senate Bill 37, which the board will discuss under Agenda Item #17, Legislative Update.

Agenda Item 6 Public Comment

Time: 10:16 a.m.

The board had three separate regulations projects out for public comment and were ready to review them. Donna Bellino clarified that the regulation project that closed for public comment on February 26, 2018, was not yet ready for review as some of the comments arrived via postal service and couldn't be included in the board packet in time.

PDMP Fee Regulations (Closed February 21, 2018)

The board first reviewed public comments relating to the proposed PDMP fee under centralized regulation, 12 AAC 02.107, which would establish an initial registration fee of \$50.00 as well as a

\$50.00 renewal fee to be paid every two years. Lana Bell commented that she has received feedback from several licensees opposing this proposal, to which Chair Holm agreed but indicated that when the bill on this was being heard, licensees didn't come forward to testify against it. Chair Holm added that because the authority for establishing fees for the database is now written in statute, the board doesn't have the ability to retract the proposed fee or to not require such. Lana Bell inquired as to whether the fee could be lowered, to which Ms. Carrillo responded that the division would be reviewing all 245 public comments before making any final determination on the proposed fees. Chair Holm prompted Ms. Carrillo for clarification as to whether the board is required to take action on the public comments, to which Ms. Carrillo indicated this was not required as the proposed change is to a centralized regulation rather than to the board's regulations under 12 AAC 52. Tammy Lindemuth inquired as to what the reason is for now charging a fee when the database has been in place since 2008, to which Chair Holm and Rich Holt stated that the database is entirely grant funded and will need to be sustained by fees. Chair Holm added that it's possible the fee could be adjusted to only cover the costs that are necessary regardless of whether there's an available grant to cover some of the costs. The board expressed interest in hearing what other states require a registration fee or renewal fee.

TASK

Laura Carrillo will send out a poll asking what states require a registration fee.

Senate Bill 74 Regulations (Pertaining to PDMP access; closed February 15, 2018)

The board then moved on to reviewing written public comments on the SB 74 regulations pertaining to PDMP requirements, including changes to:

- 12 AAC 52. 855 – Registration requirements with the PDMP
- 12 AAC 52. 860 – Access and conditions for use
- 12 AAC 52. 865 – Reporting and reviewing requirements
- 12 AAC 52. 870 – Waiver of electronic submission of data
- 12 AAC 52. 880 – Correct statute citation referencing Medicaid reform
- 12 AAC 52. 885 – Purge of database records
- 12 AAC 52. 890 – Grounds for discipline and reporting of PDMP violations
- 12 AAC 52. 920 – Disciplinary guidelines for PDMP violations
- 12 AAC 52. 995 - Definition of practitioner relating to PDMP

Chair Holm called for break at 10:50 a.m.

Off record at 10:50 a.m.

On record at 11:02 a.m.

Returning for break, the board honed in on a comment submitted by Health and Social Services, Deputy Commissioner, Jon Sherwood who wanted to bring to the board's attention a recommended citation to use in lieu of the citation in the current proposed language in 12 AAC

52.880(e). Ms. Carrillo commented that the statute in the current proposed change makes reference to AS 47.07.038, which is actually no longer in effect; Jon Sherwood recommended instead to cite AS 47.05.270. Chair Holm requested additional information on the latter statute as it is unclear as to how the statute relates specifically to the PDMP.

The board then addressed confusion of the time computation, however, it was clarified that this is already clearly articulated under 12 AAC 02.920(b).

TASK

Ms. Carrillo will ask for further clarification for DHSS on the relevance of AS 47.05.270 to the PDMP.

Agenda Item 8 **Budget Report/Division Update** **Time: 11:38 a.m.**

Melissa Dumas joined the room at 11:38 a.m.

Melissa Dumas, Administrative Officer, joined the room to provide the board's budget report for the FY18 2nd quarter. Ms. Dumas reminded the board that they're currently in a renewal year and are incurring revenue. It was added that the board has incurred \$86,000 this year but will likely bring in \$800,000 for the total year. Ms. Dumas also informed the board that their total personal services so far is \$107,837, that their travel expenses is at \$3,664, and that there is no anticipated fee increase for the board at this time.

Melissa Dumas left the room at 11:42 a.m.

Agenda Item 9 **Board Business** **Time: 11:44 a.m.**

Marilyn Zimmerman joined the room at 11:44 a.m.

Review Applications

After a concise and informative budget report, the board moved onto board business, beginning with the review of applications. Due to the nature of the discussions relating to tabled applications and default revocations, the board entertained a motion to enter executive session.

On a motion duly made by Anne Gruening in accordance with AS 44.62.310(c)(2), the board unanimously moved to enter executive session for the purpose of discussing subjects that tend to prejudice the reputation and character of any person, provided the person may request a public discussion.

Staff members, Donna Bellino, Laura Carrillo, and Marilyn Zimmerman were authorized to remain in the room.

Off record for executive session at 11:46 a.m.

On record for public discussion at 11:58 a.m.

Marilyn Zimmerman left the room at 12:16 a.m.

Upon return from executive session, Chair Holm clarified for the record that no motions were made during executive session, but indicated that the board was ready to take action on tabled applications and matters involving default revocations and a voluntary surrender.

On a motion duly made by Anne Gruening to approve the pharmacy technician application for Ric Allen in consideration of AS 08.80.261(a)(4), seconded by Phil Sanders, and opposed unanimously, it was:

RESOLVED to deny the pharmacy technician application for Ric Allen due to a felony conviction per AS 08.80.261(a)(4), which authorizes the board to deny a license if an applicant “has been convicted of a felony or has been convicted of another crime that affects the applicant’s or licensee’s ability to practice competently and safely”.

APPROVE	DENY	ABSTAIN	ABSENT
Leif Holm	x		
Richard Holt	x		
Phil Sanders	x		
James Henderson	x		
Anne Gruening	x		
Lana Bell	x		
Tammy Lindemuth	x		

No further discussion.

On a motion duly made by Rich Holt to accept the voluntary surrender of Tarnisha Bedward-Davis, seconded by Tammy Lindemuth, and approved unanimously, it was:

RESOLVED to accept the voluntary surrender of Tarnisha Bedward-Davis.

APPROVE	DENY	ABSTAIN	ABSENT
Leif Holm	x		
Richard Holt	x		
Phil Sanders	x		
James Henderson	x		
Anne Gruening	x		
Lana Bell	x		
Tammy Lindemuth	x		

No discussion.

TASK

Ms. Carrillo will be sure to add the applications for Rex Malcom and Jennifer La Tourelle for discussion at the board's next meeting.

Review Reports of Lost or Stolen Rx:

Hearing nothing further on disciplinary actions, default revocations, or voluntary surrenders, the board moved to reviewing reports of lost or stolen prescriptions. Included in the board's packet were reports submitted by the Alaska Managed Care Pharmacy #1829, Carrs Pharmacy #1812 and CVS Pharmacy #1704. Ms. Carrillo inquired to the board what the typical protocol is for reviewing these reports, and whether the board usually takes action based upon what is reported. Chair Holm clarified that these reports are only reviewed, but that action may be taken if there are outstanding concerns that warrant further investigation.

Review and Approval of Outstanding Continuing Education Audits

The board then moved on to discussion of continuing education audits from the June 30, 2016, renewal period. Donna Bellino informed the board that the certificates of completion have already been screened during a preliminary administrative review.

On a motion duly made by Rich Holt to accept the continuing education certificates for individuals with outstanding audits, seconded by James Henderson, and approved unanimously, it was:

RESOLVED to close the 2016 continuing education audits for Melanie Kluck, Heidi Brainerd, Giyae Lee-Thompson, Sean Berkey, Constance Reyes, Vincent Greear, Margaret Saam, Leanne Stephenson, Mary Bowen, David Thompson, Robert Grogan, Eric LeBoeuf, Lisa Gore, Mike Branson, Ronald Simono, John Davis, Sonja Marie Foutty, Katherine Farrington, Lester Kish, Marlene Perschbacher, Elaine Grant, Amy Rowan, Sonia Ceng, Jane Russell, Lorinda Girourard, Cynthia McCoy, Rodney Gordon, Barbara Antal, Brant Herman, David Atahey, Jamie Lynn Malstrom, Justin May, Emily Thomas, Chhayal Dalal Thomas, Wilbur Graves, Randal Brown, Jared Rawlings, Gary Scott, Jeffrey Gaarder, Alexander Kappleman, Ronald Houle, Gale Rae Berkey, Susan Wheeler, Ben Jensen, Sean Berkey, Denise Every, Kali Allen, Deborah Padilla, Elizabeth Leraas, Nancy Schaefer, Carrie Lang, Laura Olienik, Deon Pretorius, Jeffrey Stevens, Forrest Fentress, Piper Machamer, Emily Phipps, Mark Johnson, Jill Reid, Killsoo Jang, Adam Vorke, Erin Bollinger, Robyn Goff, Ryan Hardcastle, Lisa Babiak, Tolulope Balogun, Donat Doni, Ashley Kobylinski, Donald Schumacher, Jeffrey Unger, Dominique Lauten, Esnaldo Franco-Ferrer, Howard Ganser, Robert May, David Denio, Tracey Hysong, Hsiao-Lan Ng, Kim Boehmer, Julie Mannello, Joyce Schramm, Charles Barnett, Bruce Christensen, Katherine Pratt, Paul Gionet, Lori Devito, Douglas Bartko, Richard Green, Carroll Mortenson, Roger Paul Penrod, and Patrice Bohrer.

	APPROVE	DENY	ABSTAIN	ABSENT
296				
297	Leif Holm	x		
298	Richard Holt	x		
299	Phil Sanders	x		
300	James Henderson	x		
301	Anne Gruening	x		
302	Lana Bell	x		
303	Tammy Lindemuth	x		

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305 Discussion: It was noted that audits for Jessica LaTourelle and Rex Malcom would be addressed at
306 a later date.

307
308 **TASK**

309 Staff will send audit closed letters to all pharmacists whose continuing education audits have
310 closed.

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313 **Agenda Item 10**

Recess

Time: 12:48 p.m.

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315 The board recessed the meeting at 12:48 p.m. and would resume on March 1, 2018.
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DRAFT MINUTES OF THE MEETING
February 28 – March 2, 2018

By authority of AS 08.01.070(2), and in compliance with the provisions of AS 44.62, Article 6, a scheduled meeting of the Board of Pharmacy was held via WebEx and at the State Office Building, Conference Room A in Juneau, Alaska on February 28 – March 2, 2018.

These are draft minutes that have not yet been approved by the board.

Agenda Item 11 Call to Order/Roll Call Time: 9:05 a.m.

The **March 1, 2018**, meeting day was called to order by Chair, Leif Holm at 9:05 a.m.

Board members present, constituting a quorum:

Leif Holm, PharmD #PHAP1606 – *Chair*
Richard Holt, PharmD #PHAP2008, MBA – *Vice Chair*
Phil Sanders, RPh #PHAP776
James Henderson, RPh #PHAP1683
Anne Gruening, Public Member
Lana Bell, RPh #PHAP893
Tammy Lindemuth, Public Member
Sharon Long, Public Member (effective 03/01/2018; via phone)

Division staff present:

Donna Bellino, Occupational Licensing Examiner
Laura Carrillo, Records & Licensing Supervisor
Virginia Geary, Occupational Licensing Examiner, Board of Veterinary Examiners
Gail Bernth, Executive Administrator, Board of Nursing (via phone)
Debora Stovern, Executive Administrator, Medical Board (via phone)
Sher Zinn, Records & Licensing Supervisor

Public members present:

Greg Estep, #PHAP2259, Walgreens (via phone)
Jacob Cooper, Client Relations Manager, Appriss Health
Aimee Bushnell, Office of Senator Hughes
Jeremy Brown
Sara Supe, #PHAP2258
Lis Houchen, NW Regional Director, National Association of Chain Drug Stores
Hal Geiger, Board of Veterinary Examiners, Public Member
Lori DeVito, #PHAP837, Accreditation Commission for Health Care
Marny Rivera, NPC Research, PDMP – DDPI Evaluator
Christine Michetti, #VETV483

Agenda Item 12 Review/Approve Agenda

Time: 9:06 a.m.

Chair Holm addressed the agenda for March 1st and commented that the board should re-address their position on Senate Bill 32 relating to equivalent generic drugs and interchangeable biological products, which the board had previously opposed. Chair Holm entertained a motion to add this topic to Agenda Item #13, Pharmacy Industry Updates.

On a motion duly made by Leif Holm to add the topic of reassessing the board's position on Senate Bill 32 relating to biologics, seconded by Lana Bell, and approved unanimously, it was:

RESOLVED to approve the March 1, 2018, agenda as amended.

	APPROVE	DENY	ABSTAIN	ABSENT
Leif Holm	x			
Richard Holt	x			
Phil Sanders	x			
James Henderson	x			
Anne Gruening	x			
Lana Bell	x			
Tammy Lindemuth	x			
Sharon Long	x			

No discussion.

Agenda Item 13 Pharmacy Industry Updates

Time: 9:10 a.m.

Debora Stovern joined the room telephonically at 9:29 a.m.

Gail Bernth joined the room telephonically at 9:34 a.m.

Debora Stovern and Gail Bernth left the room at 12:57 p.m.

Hearing nothing further on reviewing the agenda, Chair Holm prompted discussion on updates to the pharmacy industry.

Discussion of Senate Bill 32

Chair Holm commented to the board that about a year ago, the board had written a letter in opposition to SB32, which would allow substitution of biosimilar products at a pharmacy level. Chair Holm added that one of the main points against the bill was the requirement for pharmacists to report to the physician whenever a substitution was made, which seemed to place an onerous responsibility to pharmacists. After discussing with bill sponsors the implications this bill would have, the process in actuality seemed relatively more similar. Chair Holm clarified that this would involve submitting a claim electronically through a pharmacy benefit manager (PBM) where it would be adjudicated. This method of reporting would effectively satisfy the pharmacist's reporting requirement because physicians have access to these adjudicated reports. Chair Holm further commented that if this bill passes, individuals would have access to these interchangeable drugs without putting an undue burden on pharmacists for providing alternative medications and reporting them. Based on this, Chair Holm recommended that the board support this bill.

Phil Sanders inquired what the impact would be on an institutional facility in tracking these substitutions in whether physicians have been informed when an interchangeable product has been provided. Rich Holm commented that as long as the information is submitted through an interoperable electronic medical record system, an electronic prescribing technology, a pharmacy benefits manager, or a pharmacy record, this reporting requirement will suffice. Chair Holm reiterated this, asserting that there would be nothing further that a pharmacist would need to do.

Lana Bell provided a response from a personal perspective, expressing her opposition to having to substitute one prescription before becoming eligible for the other, which seemed to unfairly be done in favor of insurance companies that may have a coverage preference. Ms. Bell emphasized her position as a private person, stating that her opinion isn't to dissuade the board from supporting this bill. Chair Holm stated that the drug does have to be an interchangeable biosimilar in order for a substitution to qualify, alluding to the idea that the specificity and efficacy profiles of the drugs, thereby eliminating concerns of lower quality medications.

Rich Holt reiterated language in the bill stating that the prescription may indicate to dispense as written, so if stated otherwise and if the prescriber has full confidence in allowing a substitution, this could be done, so long as the patient has the opportunity to provide consent. Mr. Holt commented that when you start a biologic there could be a chance of experiencing a different reaction, which is the risk one takes with chemical and physiological interactions. The board continued to discuss this bill and the implications it has on pharmacists.

On a motion duly made by Leif Holm to write a letter in support of SB 32, seconded by Rich Holt, and approved unanimously, it was:

RESOLVED to write a letter in support of SB 32.

	APPROVE	DENY	ABSTAIN	ABSENT
Leif Holm	x			
Richard Holt	x			
Phil Sanders	x			
James Henderson	x			
Anne Gruening	x			
Lana Bell	x			
Tammy Lindemuth	x			
Sharon Long	x			

No discussion.

Alaska Pharmacist Association Convention (Update from Rich Holt)

Rich Holt provided a summary of his presentation at the Alaska Pharmacist Association Convention that was held on February 10, 2018. Mr. Holt stated that he believed the presentation was well received and that it was overall a positive experience. Chair Holm agreed, adding that it resulted in good feedback from licensees. Ms. Bellino inquired what the feedback was on the technicians, to which Rich stated that he presented this topic last because he knew it was a hot topic; technicians expressed some concerns about liability, and Rich Holt stated to them that this would require a review of regulations to address those concerns. Rich added that he also commented to licensees the importance of participating in opportunities for public comments on regulations. Ms. Carrillo asked for clarification on the background of this issue, to which Rich stated that technicians are concerned that as the board re-evaluates technician regulations and moves to recognizing nationally certified technicians and adds more responsibilities to technicians that pharmacists otherwise may have done, this may inadvertently result in technicians not working due to potential liability issues. Phil Sanders commented that this is the trend in which the pharmacy industry is shifting to, and that Alaska should pursue this to stay on track. Rich Holt again reiterated the importance of engaging in public comment at the time these are solicited rather than providing feedback after the fact.

Controlled Substance Advisory Committee

Lana Bell provided an update from the November 14th CSAC meeting, of which she's a current member along eight other subject-matter experts. Ms. Bell added that the current chair of the committee is the attorney general, and the priority agenda item being addressed at this time is the scheduling of drugs on an emergency basis. Ms. Bell commented that because the dilemma of some drugs not currently controlled or otherwise considered illegal, such as kratom, efforts to take street drugs off the streets are limited because these are neither state nor federally scheduled. It was added that in order to pursue scheduling for regulating these drugs, it would require a legislative process. Ms. Carrillo commented that the bill doesn't explicitly mention AS 08.80, so resources to schedule these meetings would likely stay under the Department of Law with the attorney general rather than transferring the duties of such scheduling under the purview of the

board. Ms. Bell then stated that the committee is tracking the progress of the Office of Substance Misuse and Addiction Prevention (OSMAP), led by Andy Jones, to oversee strategic plan efforts for the opioid issue in relation to criminal justice-involved populations. Ms. Bell also informed the board that the CSAC is working with the Department of Corrections to develop treatment plans for inmates with a history of drug abuse with the ultimate goal of reducing the likelihood of recidivism and relapse upon release. With all these efforts, Ms. Bell added that OSMAP would be working to develop relevant stakeholders involved in these initiatives.

NABP Annual Meeting

The board discussed the NABP annual meeting that will be held on from May 5 – 8, 2018, in Colorado. Chair Holm inquired as to whether the NABP would cover this cost, which Ms. Bellino affirmed. Chair Holm and Phil Sanders indicated their interest in possibly attending. Lana expressed her positive experience in previously attending the meeting, and Donna Bellino indicated that a travel grant is available for an attendee from our state.

TASK

Leif Holm and Phil Sanders will provide staff with an update by mid-March as to whether they would be attending the NABP annual meeting.

Poison Prevention Packaging Act (PPPA), Investigations, and Inspections

The board reviewed documents relating to the PPPA provided by David Burns from the U.S. Consumer Protection Agency and how it relates to inspections. What David Burns is proposing is to reimburse the board for conducting inspections, however, the board may only be compelled to engage in an inspection if the issue relates to a federal law regarding the practice of pharmacy. After further review, Chair Holm noted that the document indicates the reimbursement inspection services would be only for in-state independent pharmacies and would not apply to an out-of-state pharmacy, and that the focus of the inspection would be on child-resistant packaging. Lana Bell commented that focusing only on this aspect of an inspection wouldn't be an efficient investment of the board's time. After the board discussed this opportunity, it was determined that there is no current need for this service. Chair Holm stated that the need is for assistance with in-state inspections, not for out-of-state inspections who are already required to submit inspection reports from their

The board also discussed the differences between investigations and inspections. It was clarified for Ms. Carrillo that the two are separate, but that latter is not regularly done even though the board has the authority to provide inspections under AS 08.80.030(b)(3) with inspectors defined under 12 AAC 52.995. Inspections have been geographically limited to the Anchorage area because of the lack of resources to send inspectors to other parts of the state.

TASK

Laura Carrillo will follow-up with David Burns on the board's discussion of the PPPA and reimbursement proposal.

Chair Holm called for break.

Off record at 10:14 a.m.

On record at 10:25 a.m.

Prescription Drug Monitoring Program

Laura Carrillo provided an update on the PDMP by first providing a summary of new registration, prescription, and dispensation data. Ms. Carrillo then gave the board a summary of her PDMP presentation from the Connecting with Data 2018 Pre-Summit Conference in Anchorage on January 15th. Ms. Carrillo informed the board that the presentation included a summary of PDMP goals, a timeline of database implementation, interaction requirements, database enhancements such as prescriber report cards, and challenges such as identifying individuals who are required to register. Chair Holm inquired as to whether we know if we're at 100% registration, or in other words if we know whether all licensees required to register are in fact registered. Ms. Carrillo stated currently, the PDMP doesn't have a license integration feature and that CBPL doesn't track DEA registrations. This makes it difficult to capture all the currently active licensees who also hold an active DEA registration, which is the criteria used to determine whether a practitioner is required to register with the database. Jacob Cooper added that Appriss Health works with 42 other states and tracking who and who isn't required to register or review patient prescription history is a ubiquitous challenge, but this is an aspect that the board can improve on with the assistance of Appriss. Another concern was the issue of purging records, which Chair Holm stated was a finding made during the board's last legislative audit. Jacob Cooper stated the purging of records can be arranged based upon Alaska's needs and obligations. With regards to prescriber reports, Ms. Carrillo stated that secondary specialties are used as a comparison measure on prescriber reports and Jacob Cooper commented that Appriss is currently exploring a way to compare prescribing practices on the tertiary specialty level.

Hal Geiger, public member with the Board of Veterinary Examiners commented that veterinarians face unique challenges because of their patient base and identifying them. Mr. Geiger inquired whether it was known how many veterinarians are registered and whether they're complying, to which Ms. Carrillo stated that approximately 80% of licensed veterinarians are registered, but that knowing whether they're compliant would require an audit. Christine Michetti, veterinarian, stated that the specific challenge in identifying patients is the birthdate and name. The board discussed this concern and the unique challenges the veterinarian board faces. Jacob Cooper added that AWARe has a power algorithm to determine whether one pet is the same pet as another, and providers can also consolidate accounts when aspects of a pet's profile differs slightly, e.g.: misspellings in name or change in birth date. Ultimately, the Board of Veterinarian Examiners can establish regulations for identifying patients. Dr. Michetti expressed concern of veterinarians being disciplined for not catch pet owners who divert drugs. Chair Holm commented that at minimum, practitioners only do their due diligence to review a patient's prescription history, so if a veterinarian isn't able to catch a pet owner who abuses their animal's prescriptions or diverts them, they are still fulfilling their obligation to review the database. Chair Holm added that as long as the veterinarian is registered and reviews as required, they shouldn't be worried of being noncompliant

with the PDMP interaction requirements. The board discussed limitations of supply for veterinarians, which Ms. Carrillo stated is limited to a seven-day supply for an initial opioid prescription for animal patient. Dr. Michette stated that veterinarians sometimes prescribe more than a seven-day supply, which Chair Holm stated that this should be charted in clinic notes when a supply exceeds the initial limitation.

On PDMP data updates, Ms. Carrillo commented that since 2016, registrations have doubled and review of patient prescription history has increased substantially, with the peak coinciding with the date in which mandatory review requirements went into effect in July, 2017. Ms. Carrillo also stated that registrations appear to be going down slightly since the effective date, to which James Henderson inquired as to whether this may be due people leaving the state. Ms. Carrillo acknowledged this, stating that the data isn't population adjusted but is a good aspect to consider. It was further added that some information provided in the PDMP report is also included in and expounded upon within the 2018 legislative report.

Ms. Carrillo then moved on to forms that would be created as a result of the PDMP receiving its own program in the CBP licensing database, which is the current intent moving forward. Forms would include an initial payment form, renewal payment form, and PDMP change in status form. Ms. Carrillo stated that practitioners choose not to renew their professional license or DEA registration, their access to the PDMP should be inactivated, so the status form would prompt this account change. Similarly, delegates who are no longer employed by a certain provide should also not have access to the PDMP.

Ms. Carrillo then addressed the legislative report for the board's review and approval, which includes a summary of the database and information on the PDMP vendor and platform, Appriss Health and AWAReE, respectively. Additionally, the legislative report includes updates on the board's progress with regards to overseeing registration requirements and completing deliverables as a result of receiving federal grants, including creating an awareness survey and feedback questionnaire as a result of a receiving a Data Driven Prevention Initiative (DDPI) grant from the CDC. Marny Rivera, an evaluator contracted by DHSS was on the line to comment on the need for board member interviews in gauging progress with the PDMP and collaboration with DHSS. The board continued to review the legislative report and ultimately decided that a few topics should be added before the board approves it.

Rich turned the board's attention to data access, citing AS 17.30.200(j) indicated that the board is to notify any person whose prescription information is improperly accessed. Ms. Carrillo stated that the board has not yet done this and there is not an established standard for notifying patients. The board discussed inadvertent consequences of contacting a patient to inform them of the information that was inappropriately accessed as this could potentially be a confidentiality breach issue, or nonetheless very sensitive. The board requested a legal opinion on this statute.

TASK

Laura Carrillo will request a legal opinion on AS 17.30.200(j), specifically what the board is required to do and how this should be carried out.

TASK

Laura Carrillo will add information to the legislative report regarding mass mail-outs to unregistered licensees

TASK

Leif Holm will contact Marny Rivera to participate in a board member interview for the DDPI grant.

Accreditation Commission for Health Care

Lori Devito presented to the board information on ACHC's PCAB accreditation, which Ms. Devito clarified is not an inspection—that it actually exceeds qualities of inspections—and that ACHC is not a regulatory agency, but an entity that establishes standards that state regulatory agencies can choose adopt. Ms. Devito added that PCAB accreditation is a program that the commission acquired in 2014, and that results aren't sent to the board but can be if required or recommended by the board. Some states have required PCAB accreditation, such as Michigan, but ACHC ultimately encourages this accreditation as a standard for compounding pharmacies rather than encourages that this standard be put in statute or regulation. Ms. Devito further added that a big focus on ACHC is quality control and that they provide workshops for pharmacists. Ms. Devito summarized the PCABP process and stated the cost is approximately \$8,500, which is incurred by individual pharmacies, not by the state. Chair Holm commented that this is a top notch company, and encouraged the board to support ACHC PCAB as a compounding pharmacy standard. Rich Holt commented that inspections from out-of-state pharmacies are only required to submit inspections from their home jurisdiction that was completed within the two years preceding their application, alluding to the need to clarify whether this standard could be implemented even for out-of-state pharmacies.

Chair Holm called for break.

Off record at 12:05 p.m.

On record at 12:13 p.m.

Appriss Health

Jacob Cooper introduced himself as the client relations manager for Alaska, informing the board that Appriss started in Alaska back in 1999 with a victim notification program partnership with the Alaska Department of Corrections. Chair Holm inquired about this program, and Jacob Cooper stated that this is the first program in which Appriss began working with sensitive data; the victim notification program sends updates to victims when their perpetrator is released from jail, goes on probation, or are otherwise recorded by the criminal justice system as having a new action. Jacob cooper then moved on to the PDMP program in Alaska, including updates on PMP InterConnect, PDMP milestones, registration growth and interaction statistics—pointing out that activity tends

to dip in December during the holidays, relevant statute changes, clinical alerts, EHR integration, and NarxCare. Chair Holm inquired about sharing PDMP data with other states through PMP InterConnect, to which Ms. Carrillo stated that the data sharing is done only after a memorandum of understanding (MOU) is signed. Ms. Carrillo stated that an MOU was signed in 2015, and Tammy Lindemuth inquired as to what states we are currently sharing with. Alaska shares data with seven other states, however, Chair Holm expressed concern about this since Alaska is a private state, meaning residents tend to be more private, and that patients may not know that their information can be accessed from other states. Jacob Cooper clarified that Alaska patient information can't be exported from the PDMP into another state's database, but that PMP InterConnect essentially creates a secure channel for other states to simply view the data. Chair Holm emphasized the need to address this at the division level and to explain this access in the legislative report.

The board was also particularly interested in looking further into the NarxCare program. NarxCare is a holistic substance misuse platform that helps practitioners interpret data in a meaningful and fast way by providing a report at the treatment setting (Figure 1). A NarxCare report shows risk scores for narcotics, stimulants, and sedatives, overall improving saliency of red flags. Jacob Cooper commented that what Appriss has observed is that a lot of overdoses don't have prescriptions at the time of overdose; they get the prescription, then get a hold of street drugs, then have an overdose after their prescription is no longer active. An additional function of NarxCare is to prompt practitioners to recommend treatment facilities, so Appriss is currently working with Medicaid assisted treatment centers. Lana Bell inquired as to what the cost of the program is, to which Jacob Cooper clarified that it depends on the number of licensees a state has.

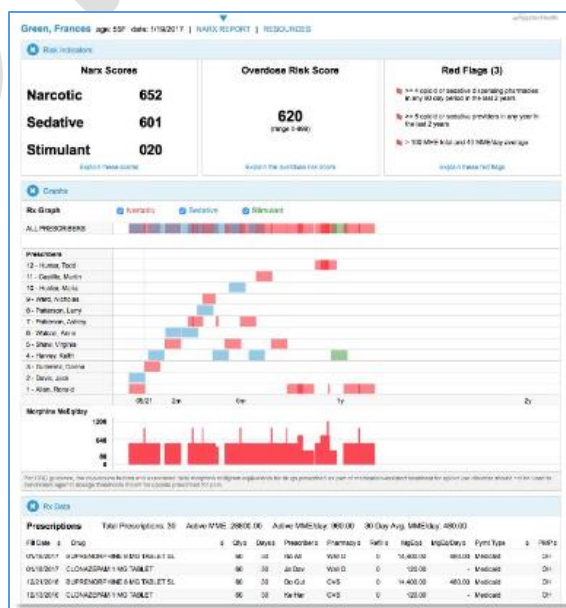
TASK

Laura Carrillo will look further into PMP InterConnect and will include a section of this in the legislative report.

TASK

Laura Carrillo will look into the cost of NarxCare as an enhancement to the PDMP.

Figure 1. NarxCare report



Agenda Item 14 Recess

Time: 12:57 p.m.

After the PDMP update, Phil Sanders and Chair Holm called for recess at 12:57 p.m.

DRAFT

State of Alaska
Department of Commerce, Community and Economic Development
Division of Corporations, Business and Professional Licensing

Alaska Board of Pharmacy

DRAFT MINUTES OF THE MEETING
February 28 – March 2, 2018

By authority of AS 08.01.070(2), and in compliance with the provisions of AS 44.62, Article 6, a scheduled meeting of the Board of Pharmacy was held via WebEx and at the State Office Building, Conference Room A in Juneau, Alaska on February 28 – March 2, 2018.

These are draft minutes that have not yet been approved by the board.

Agenda Item 1 Call to Order/Roll Call Time: 8:58 a.m.

The **March 2, 2018**, meeting day was called to order by Chair, Leif Holm at 8:58 a.m.

Board members present, constituting a quorum:

Leif Holm, PharmD #PHAP1606 – *Chair*
Richard Holt, PharmD #PHAP2008, MBA – *Vice Chair*
Phil Sanders, RPh #PHAP776
James Henderson, RPh #PHAP1683
Anne Gruening, Public Member
Lana Bell, RPh #PHAP893
Tammy Lindemuth, Public Member
Sharon Long, Public Member (effective 03/01/2018; via phone)

Division staff present:

Donna Bellino, Occupational Licensing Examiner
Laura Carrillo, Records & Licensing Supervisor
Jun Maiquis, Regulations Specialist

Public members present:

Greg Estep, #PHAP2259, Walgreens (via phone)
Dirk White

Agenda Item 14 Review/Approve Agenda

Time: 9:06 a.m.

Chair Holm addressed the agenda for March 2nd and commented that the board should establish the board's new secretary.

On a motion duly made by Lana Bell to add voting of a board secretary to the agenda, seconded by Rich Holt, and approved unanimously, it was:

RESOLVED to approve the March 2, 2018, agenda as amended.

	APPROVE	DENY	ABSTAIN	ABSENT
Leif Holm	x			
Richard Holt	x			
Phil Sanders	x			
James Henderson	x			
Anne Gruening	x			
Lana Bell	x			
Tammy Lindemuth	x			
Sharon Long	x			

No discussion.

Agenda Item 15 Board Business

Time: 9:06 a.m.

Board Positions

The board moved to voting on a board secretary.

On a motion duly made by Lana Bell to vote Tammy Lindemuth as the board secretary, seconded by Rich Holt, and approved unanimously, it was:

RESOLVED to elect Tammy Lindemuth as the board secretary effective 03/02/2018.

	APPROVE	DENY	ABSTAIN	ABSENT
Leif Holm	x			
Richard Holt	x			
Phil Sanders	x			
James Henderson	x			
Anne Gruening	x			
Lana Bell	x			
Tammy Lindemuth	x			

No discussion.

Legislative Report

Sharon Long inquired as to whether the board would be reviewing and approving the legislative report that was drafted by Ms. Carrillo, to which Chair Holm commented that in the interest of time, the board would be reviewing and approving via an email ballot.

Board Contacts

Leif Holm and Rich Holt will continue to serve as legislative contacts on behalf of the board.

Dirk White joined the room at 9:28 a.m.

Review Legislation

Chair Holm then prompted the board to discuss the various pieces of legislation that the board is affected by, as well as legislation that the board is tracking as FYI bills.

- HB9/SB37: Pharma BD & Employees; Drug Dist/Manu
 - Licensing of out of state wholesale distributors and providing for an executive administrators
 - Already passed the Senate, needs hearing in House Finance
 - Would require substantial regulations
- HB43: New Drugs for the Terminally Ill
 - Passed House unanimously
 - FYI
- HB90: Occ. Licensing Fees; Investigation Costs
 - Withdrawn effective 02/23/2018
- HB262: Military Spouse Courtesy License
 - DCCED would have to report licenses to joint committee each year
 - Submit report to legislature
 - Must provide a temporary license
 - FYI
- SB32: Prescriptions for Biological Products
 - Board changed position in support of bill
 - Would require regulations

Anne Gruening joined the room at 10:00 a.m.

- SB79: Opioids; Prescriptions; Database; Licenses
 - Not an active bill
 - Similar to HB 159 language

- SB112: Workers Compensation; Drug Database
 - Intent is to get folks back to work and reduce dependency on opioids
 - Is a priority of the Alaska Chamber of Commerce
 - Reduce unproductive litigation; attempts to shift time and money from workers comp board and onto effective and impartial administrative procedures
- SB146: AG Schedule Controlled Substances
 - Changes chair of CSAC from attorney general to president of Board of Pharmacy or president's delegate
 - Participate in emergency scheduling of drugs
- HB326/SB120: Naturopaths; Licensing; Practice
 - Would give prescriptive authority to naturopaths
 - FYI
- SB209: Prescription Drug Pricing
 - Scheduled for hearing on March 7th, 2018
 - Already in practice that pharmacists disclose and document price for out-of-pocket and retail

Dirk White left the room at 10:12 a.m.

Chair Holm called for break.

Off record at 10:13 a.m.

Anne Gruening left the room at 10:23 a.m.

On record at 10:27 a.m.

Agenda Item 6 Public Comment

Time: 10:27 a.m.

The board returned to reviewing public comments, which was first addressed on day 1 of the meeting. Having already reviewed public comments relating to PDMP use and access. As well as comments relating to the PDMP fees, Chair Holm prompted the board to address the public comments that ended on February 26, 2018, including:

- 12 AAC 52.120 - Review of pharmacist intern license application, is proposed to be changed to amend the checklist requirements for pharmacist intern license application.
- 12 AAC 52.130 - Registration of pharmacies located outside of the state, is proposed to be changed to clarify the provisions related to applications for registration of pharmacies located outside of this state.
- 12 AAC 52.200 - Pharmacist-in-charge, is proposed to be changed to amend the requirements for a pharmacist designated to replace the pharmacist-in-charge of a pharmacy.

- 12 AAC 52.240 - Pharmacist collaborative practice authority, is proposed to be changed to amend the pharmacist collaborative practice authority requirements.
- 12 AAC 52.470 - Refills, is proposed to be changed to amend the provisions related to prescription drug order refills.
- 12 AAC 52.510 - Substitution, is proposed to be changed to clarify the provisions related to notes or wording on the prescription drug order.
- 12 AAC 52.610 - Wholesale drug distributor license, is proposed to be changed to amend the provisions related to a change in facility manager.
- 12 AAC 52.991 - Disciplinary decision or conviction reporting requirement, is proposed to be changed to add the requirement that a licensed or registered facility report in writing to the board any disciplinary decision or conviction

James Henderson addressed the proposed changes 12 AAC 52.470 pertaining to refills, inquiring what the rationale for the 30 days was, to which Chair Holm stated that the intent was to see whether a patient does well with this day supply before providing for a longer supply. Phil Sanders pointed to a study included along with one of the comments, stating that patients with 90-day refills had greater medication adherence, greater persistency, normal wastage, and greater savings. Rich indicated that it is a restriction, so it might be reasonable to expand to 90 days. The board deliberated on whether to extend to 90 days or to 100 days.

The board then discussed proposed changes to 12 AAC 52.120, which would require a pharmacy intern to submit a certificate of moral character from two reputable citizens. Some comments on this proposed regulation included concern that this requirement would add to the already delayed processing of inter applications. Ms. Bellino commented that with the addition of the jurisprudence questionnaire, the processing time can now be more efficient as this eliminates waiting time; prior to the board's resolution at the November - December 2017 meeting to include the jurisprudence questionnaire, the questionnaire was to applicants after their documents were received. Lana Bell stated that currently, intern licenses aren't issued until one month before their rotation is supposed to start, to which Ms. Bellino stated this is the timeline that has always been in place. Ms. Carrillo inquired as to whether this requirement is in regulation or an established preference by the board. Rich Holt and Ms. Bellino stated that this has been the typical process, but Ms. Carrillo suggested that the licenses be issued upon completion rather than waiting until a month before a rotation begins. Chair Holm prompted the discussion to focus back on the public comment concern of processing time. Ms. Bellino stated that the certificates of moral character could be included in the application itself, so it wouldn't really add to the processing delay.

TASK

Ms. Carrillo will discuss with the other records & licensing supervisor who supervises pharmacist interns and technicians the idea of issuing intern licenses upon application completion rather than one month prior to the intern's rotation.

After reviewing public comments to the proposed regulations, Chair Holm called for motions.

On a motion duly made by Rich Holt that in light of public comment, to accept regulations 12 AAC 52.120 (pharmacy intern application), 12 AAC 52.130 (review of applications of pharmacies located outside of the state), 12 AAC 52.200 (pharmacists-in-charge), 12 AAC 52.240 (pharmacists collaborative practice authority), 12 AAC 52.510 (substitution), 12 AAC 52.610 (wholesale drug distributor), 12 AAC 52.991 (disciplinary decision or conviction reporting); to amend 12 AAC 52.470(d) to state: "If an original prescription order is prescribed as a 30-day supply, the pharmacist may dispense up to a up to a 100-day supply"; and to strike 12 AAC 52.470(d)(1), seconded by Tammy Lindemuth, and approved unanimously, it was:

RESOLVED to accept proposed regulations 12 AAC 52.120, 12 AAC 52.130, 12 AAC 52.200, 12 AAC 52.240, 12 AAC 52.510, 12 AAC 52.610, and 12 AAC 52.991 as written in the public notice, and to accept 12 AAC 52.470(d) as amended.

	APPROVE	DENY	ABSTAIN	ABSENT
Leif Holm	x			
Richard Holt	x			
Phil Sanders	x			
James Henderson	x			
Anne Gruening	x			
Lana Bell	x			
Tammy Lindemuth	x			
Sharon Long	x			

No further discussion.

On a motion duly made by Rich Holt to amend the proposed language to 12 AAC 52.885(e) by replacing the statute citation, AS 47.07.038 with AS 45.05.270, and to accept 12 AAC 52.860, 12 AAC 52.865, 12 AAC 52.870, 12 AAC 52.880, 12 AAC 52.890, 12 AAC 52.920, and 12 AAC 52.995 as written, seconded by Tammy Lindemuth, and approved unanimously, it was:

RESOLVED to accept the proposed change to 12 AAC 52.885 as amended and to accept 12 AAC 52.860, 12 AAC 52.865, 12 AAC 52.870, 12 AAC 52.880, 12 AAC 52.890, 12 AAC 52.920, and 12 AAC 52.995 as written in the public notice.

	APPROVE	DENY	ABSTAIN	ABSENT
Leif Holm	x			
Richard Holt	x			
Phil Sanders	x			

1013	James Henderson	x
1014	Anne Gruening	x
1015	Lana Bell	x
1016	Tammy Lindemuth	x
1017	Sharon Long	x

No further discussion.

Jun Maiquis entered the room at 10:58 a.m.

Jun Maiquis entered the room at 10:58 a.m. Leif inquired whether new public comment is needed if a change is being made based on the comments. Jun Maiquis indicated that another round for public comment is unnecessary as long as the intent of the proposed changes doesn't change. Mr. Maiquis stated that the Department of Law will determine whether the intent changed as a result of amendments made after consideration of public comment.

Jun Maiquis left the room at 11:03 a.m.

TASK

Ms. Carrillo will forward the board's resolutions to the proposed regulation changes to the regulations specialist for implementation.

Agenda Item 9

Board Business

Time: 11:44 a.m.

The board resumed board business.

Annual Report

Rich Holt, Laura Carrillo, and Donna Bellino will collaborate to work on the annual report due June 1st.

Wall Certificates

Chair Holm signed wall certificates.

Upcoming Travel

The board addressed travel opportunities, including the NABP Annual Meeting that will be held in May in Colorado. Leif Holm and Phil Sanders reiterated that they would inform the staff whether they could attend by mid-March. A conference in Atlanta titled, The National Rx Abuse and Heroin Summit was also brought to the board's attention, and Lana Bell expressed her interest in attending on behalf of the board and in her role as a Pharmacy Board designee on the Controlled Substance Advisory Committee. Chair Holm inquired as to how attendance would be of benefit, to which Lana stated that some of the topics discussed during CSACs include complex issues that Ms. Bell would be able to discuss at a more involved level if she had a better understanding of

opioid issues. Ms. Bell believes that attendance at this conference would enable more active participation and contribution to the committee.

TASK

Ms. Carrillo will submit a travel approval request for Lana Bell to attend the National Rx Drug Abuse and Heroin Summit from April 2 – 5, 2018 in Atlanta, GA

Reschedule May Meeting

Due to time conflicts with board member and Ms. Carrillo's schedules, the board rescheduled their next meeting to be held on May 10th all day and May 11th half day.

Correspondence

The board received a piece of correspondence from a physician who expressed concerns about the DEA registration number being conspicuously displayed on the prescriber report. The board discussed possibilities of altering the format and available information on the prescriber report, however, it was noted that this particular concern on this matter has been the only one brought forward for their attention thus far. In addition, the board acknowledged that DEA numbers are included on prescriptions, and that including this number is not a violation of HIPAA. Since there doesn't appear to be more widespread concern of DEA confidentiality, there didn't appear to be sufficient justification for requesting a change order from Appriss Health. The board still encouraged staff to find out the cost of this, which was alluded to earlier by Jacob Cooper as being a fairly expensive change.

TASK

Ms. Carrillo will inquire about the cost of obscuring DEA registration numbers on the prescriber report.

In the interest of time, the board entertained a motion to table outstanding topics that were scheduled for discussion under Old Business.

On a motion duly made by Leif Holm to table pharmaceutical waste and disposal, compounding regulations, proof of satisfactory documentation form draft, and the IHS pharmacist form draft until the next meeting, seconded by Phil Sanders, and approved unanimously, it was:

RESOLVED to table the topics listed under Old Business for discussion at the May 10 – 11, 2018, meeting.

	APPROVE	DENY	ABSTAIN	ABSENT
Leif Holm	x			
Richard Holt	x			
Phil Sanders	x			

1097	James Henderson	x
1098	Anne Gruening	x
1099	Lana Bell	x
1100	Tammy Lindemuth	x
1101	Sharon Long	x

1102
1103 No further discussion.

1104
1105 **Agenda Item 16 Adjourn** **Time: 11:30 a.m.**

1106
1107 Hearing nothing further, Chair Holm entertained a motion to adjourn.

1108
1109 **On a motion duly made by Tammy Lindemuth to adjourn the meeting, seconded by Lana**
1110 **Bell, and approved unanimously, it was:**

1111
1112 **RESOLVED to adjourn the meeting at 11:30 a.m.**

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1114
1115
1116
1117 _____
1118 Laura Carrillo, Records & Licensing Supervisor

1119
1120
1121 _____
1122 Rich Holt, Chair